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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
| 10/656,222 | 09/08/2003 | Morton M. Mower | 302527US78 | 1067 |
| 22850 7590 09/26/2007 OBLON, SPIVAK, MCCLELLAND MAIER & NEUSTADT, P.C. 1940 DUKE STREET ALEXANDRIA, VA 22314 | | | | |
| | | | EXAMINER KAHELIN, MICHAEL WILLIAM | |
| | | | ART UNIT 3762 | PAPER NUMBER |
| | | | NOTIFICATION DATE 09/26/2007 | DELIVERY MODE ELECTRONIC |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary

Application No.

10/656,222

Applicant(s)

MOWER, MORTON M.

Examiner

Michael Kahelin

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3762

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 August 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3, 20, 27, 28, 34 and 65-73 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3, 20, 27, 28, 34 and 65-73 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date: _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date: _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 1, 2, 3, 20, 27, 28, 34, and 65-73 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In regards to claims 1 and 67, the "first axis" is indicated as "spanning anterior and posterior extremes of a right ventricular septum," in reference to Figure 1 of Applicant's disclosure. It is unclear whether the right "ventricle electrode" (138) actually lies on the interventricular septum because it appears to only contact the right ventricle outer wall. As such, the Examiner is interpreting an axis that spans the anterior and posterior extremes of a right ventricular septum to include the apex region, as shown in Figure 1.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States

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only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

4. Claims 1, 2, 3, 20, 27, 28, 65, 67-71, and 73 are rejected under 35 U.S.C. 102(e) and 35 U.S.C. 102(a) as being anticipated by Levine (US 6,473,645, hereinafter "Levine").

5. In regards to claims 1 and 67, Levine discloses a method/device for monitoring hemodynamic performance comprising positioning signaling electrodes along a first and second axis (see below), receiving electrical signals indicative of hemodynamic performance (abstract), and delivering stimulation in response to the signals in response to commands from a processor (60). Please note that the claims do not require multiple electrodes on either of the two axes. Further, based on the common usage of the term, and comments made during the interview of 9/1/2007, an "axis" does not require structure, but is merely an imaginary line. As such, an arbitrary axis can be applied to a single electrode that meets the claim limitations, and is shown in the figure below.

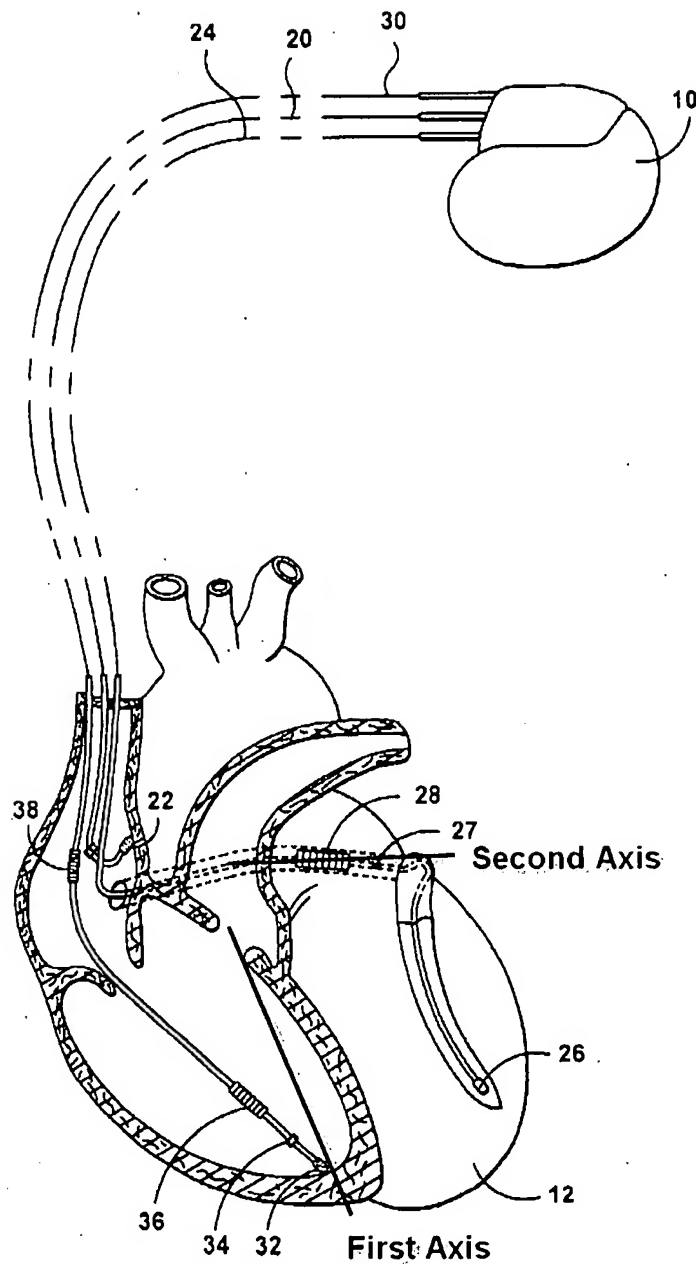


FIG. 1

6. In regards to claims 2 and 68, signals are received from the atrium (22, 82, 204, and 216).

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7. In regards to claims 3 and 69, signals are received from the left ventricle (25-29).
8. In regards to claims 20 and 70, the electrodes are placed endocardially (Figs. 1 and 3).
9. In regards to claims 27 and 71, the electrodes are placed in a coronary vein (25-29).
10. In regards to claim 28, a signaling electrode is on a lead passing through the SVC, the right atrium, ostium of the coronary sinus, and a coronary vein (21 and 24).
11. In regards to claims 65 and 73, one of the plurality of electrodes is located within the entrance of the coronary sinus along the first axis (21 and 24).

Claim Rejections - 35 USC § 103

12. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

13. Claims 34, 66, and 72 are rejected under 35 U.S.C. 102(a/e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Levine. Levine discloses stimulating a first electrode in the interventricular septum (32), and a second electrode in a coronary vein (25-29). Electrode 32 is located in the interventricular septum inasmuch as the stimulation location disclosed by Applicant in Figure 1. Alternatively, Levine discloses the essential features of the claimed invention except for stimulating an electrode in the interventricular septum. It is well known in the art to stimulate the

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interventricular septum to provide the predictable result of coordinating the contraction of the left ventricle without causing the problems associated with thromboses resulting from direct left ventricle implantation. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Levine's invention by stimulating the interventricular septum to provide the predictable result of coordinating the contraction of the left ventricle without causing the problems associated with thromboses resulting from direct left ventricle implantation.

14. Additionally, Levine discloses that the electrodes are at equidistant locations along the first and second axes because there is no requirement that multiple electrodes are on either of the axes (i.e. there is no requirement that electrodes be equidistant from other electrodes), only that the *entire system* has multiple electrodes. As such, the two electrodes are equidistant from an arbitrary point in between the two electrodes lying on different axis (i.e. the midpoint between the two electrodes).

Alternatively, Levine discloses the essential features of the claimed invention except for electrodes positioned at equidistant locations along an axis. It is well known in the art to provide electrodes at equidistant locations along an axis to provide the predictable result of mapping the electrical characteristics of a given area of the heart. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Levine's invention by providing electrodes at equidistant locations along an axis to provide the predictable result of mapping the electrical characteristics of a given area of the heart.

Response to Arguments

15. Applicant's arguments with respect to claims 1, 2, 3, 20, 27, 28, 34, and 65-73 have been considered but are moot in view of the new ground(s) of rejection, necessitated by amendment.

Conclusion

16. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Mathis et al. (US 6,643,546) is one of many teachings of equidistantly spaced electrodes and septal placement. Audoglio (US 6,556,874) is one of many teachings of electrodes placed *in* the septum.

17. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Kahelin whose telephone number is (571) 272-8688. The examiner can normally be reached on M-F, 9-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on (571) 272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

MWK

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9/17/07

Angela D. Sykes

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